K073243

Reliance Orthodontic Products, Inc.
Toll Free 1-800-323-4348 · Phone 630-773-4009 · Fax 630-250-7704
PO Box 678 · Itasca, IL · 60143 · U.S.A.

FEB - 8 2008

Section 5.0
510 (k) Summary

Note: This summary is provided in accordance with the requirements of 21CFR807.92 (c).

510 (k) Owners Name:	Reliance Orthodontic Products, Inc. Paul Gange, President
Address:	1540 West Thorndale Avenue Itasca, Il 60143 USA
Phone Number:	630-773-4009
Fax Number:	630-250-7704
Contact Person:	Paula Wendland, Regulatory Affairs Manager (Preparer)

Date 510 (k) Summary was Updated: January 30, 2008

Medical Device Name:

- Trade name – LED PRO SEAL®
- Common name – Tooth Surface Sealant
- Classification name – Coating Material for Resin Fillings (21CFR872.3310, Product Code EBD, Class II Device)

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCE IS CLAIMED (PREDICATE DEVICE) [807.92(a) (3)]:

- PRO SEAL® (510(k) submission K021503 under the Bisco, Inc. Uninhibited product)

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DESCRIPTION OF THE APPLICANTS DEVICE:

LED PRO SEAL® is a fluoride containing light cure filled surface sealant provided in a light impervious bottle dispenser. Upon delivery of one drop of LED PRO SEAL to a mixing pad, a thin coat of LED PRO SEAL is applied to a prepared enamel surface using a brush applicator and light cured for a minimum of 20 seconds with any halogen, plasma arc or cordless light capable of a 440-490 NM wavelength.

INTENDED USE AND POPULATION:

LED PRO SEAL is intended to seal enamel surfaces around orthodontic brackets. The intended patient population ranges from pediatric to adult recipients of orthodontic or dental treatment.

TECHNOLOGICAL AND PERFORMANCE CHARACTERISTICS:

Performance Characteristics of Reliance LED PRO SEAL versus original Reliance PRO SEAL®:

Property	LED PRO SEAL®	Original PRO SEAL®
Intended Use	Light Cure Filled Surface Sealant of enamel	Light Cure Filled Surface Sealant of enamel
Mechanical / Physical Properties	• Light Cure surface sealant with any halogen, plasma arc or 440-490 nm cordless LED curing light • Fluoresces when exposed to a blacklight.	• Light Cure surface sealant with any halogen or 380-420 nm cordless LED curing light. • Fluoresces when exposed to a blacklight.
Chemical Composition	Acrylate-based Resin with photoinitiator, fluorescing and fluoride releasing agent	Acrylate-based Resin with photoinitiator , fluorescing and fluoride releasing agent

Shear bond strength, Compressive strength, flexural strength, cumulative fluoride release and depth of cure testing comparisons conducted between

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LED PRO SEAL® and the predicate device, original PRO SEAL® demonstrate that the applicant device is equivalent to the legally marketed device in terms of effectiveness.

Additionally, toxicity testing was conducted by a Cytotoxicity Study using the ISO 10993-5 Agarose Overlay Method (Solid). LED PRO SEAL was found to cause mild cell lysis or toxicity (generating grade 2 for mild reactivity). LED PRO SEAL met the requirements of ISO10993-5 for a grade 2 material showing evidence that the product is safe to use. Sufficient labeling is provided for proper use and indications.

Paula Wendland
Regulatory Affairs Manager
Reliance Orthodontic Products, Inc.
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Fax: 630-250-7704

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2008

Mr. Paul Gange
President
Reliance Orthodontic Products, Incorporated
1540 West Thorndale Avenue
Itasca, Illinois 60143

Re: K073243
Trade/Device Name: LED PRO SEAL®
Regulation Number: 21 CFR 872.3310
Regulation Name: Coating Material for Resin Fillings
Regulatory Class: II
Product Code: EBD
Dated: February 1, 2008
Received: February 1, 2008

Dear Mr. Gange:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SECTION 6.0 INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): ___K073243_____

Device Name: _____LED PRO SEAL®_____

Indications for Use:

LED PRO SEAL® is intended to seal enamel surfaces around orthodontic brackets.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073243